REMARKS

The Applicant has reviewed the Office Action mailed August 14, 2007. Responsive to that Action, the present Listing of Claims is presented to replace all prior listings. Compared to previous versions:

a) claims 1-28 were canceled in a previous paper;

b) claims 29-38, 40-48, 56-67, and 75–140 are withdrawn;

c) claims 39, 49-55, and 68-74 were previously presented and remain pending in the present application; and

c) claims 141-150 are new.

In the Action, the Examiner contends that twenty distinct invention "groups" are present. In response, the Applicant provisionally elects the Examiner-identified Group 5 (claim 39) with traverse. Based on the arguments that follow, it is believed that at least the requirement for restriction as to Examiner-identified Groups 14 and 15 should be withdrawn. Therefore, substantive examination of the group 5 claims, the remaining group 14 and 15 claims, and the new claims presented herewith and as summarized above is respectfully requested.

First, it is noted that new claims 141- 150 are presented herein, directed to an isolated polypeptide or protein as set forth in claim 39 (claims 141-148), to a method of making that polypeptide or protein (claim 149) and to a polypeptide or protein so made (claim 150). No new matter is added, as the subject matter of claims 141-147 merely reflects the subject matter set forth in claims 49-55 as filed, but claiming dependency from claim 39. Claim 148 recites a pharmaceutical composition comprising the polypeptide or protein of claims 141-147 in association with a pharmaceutical carrier (see claims 49 and 68 as filed). Claim 149 recites a process for preparing an isolated polypeptide or protein according to claim 39, and is fully supported by the present Specification (see at least Example 7 of the present Specification, beginning at *page 33*). Claim 150 recites a polypeptide or protein produced by the method set forth in claim 149, and is fully supported (see at least Example 7).

The above traversal is based on the Applicant's belief that the Examiner's finding of lack of

unity of invention is improper at least in part under both PCT and U.S. PTO rules and practice. In making a finding of lack of unity of invention, it is the Examiner's burden to provide an explanation of why each group of claims lacks unity with each other group (i.e., why there is no single general inventive concept specifically describing the unique special technical feature of each group). PCT Rule 13.1, 13.2, see also Manual of Patent Examining Procedure (MPEP) §1850. Further, the MPEP specifically provides that "... lack of unity of invention ... should neither be raised nor maintained on the basis of a narrow, literal, or academic approach..." and that "... each case should be considered on its merits, the benefit of any doubt being given to the applicant." See MPEP §1850 and PCT International Search and Preliminary Examination Guidelines Chapter 10, ¶10.04. It is believed that the Examiner has not properly supported the finding of lack of unity of invention under this standard, and that the benefit of the doubt has not properly been given to the Applicant. Specifically, it is believed that at the least, the claims of the Examiner-identified Groups 5, 14, and 15 are properly directed to a single general inventive concept as defined by PCT Rule 13.1. Accordingly, the Applicant respectfully requests reconsideration of the lack of unity of invention finding and examination of all the remaining claims in this application.

Reconsideration of the restriction requirement is believed to be merited at least because the non-withdrawn claims placed in Examiner-identified Groups 14 and 15 are clearly directed to the same or similar polypeptide or protein as is recited in claim 39 (Examiner-identified Group 5), that is, an isolated growth hormone polypeptide or protein variant having the substitution Ile179Met. Representatively, the Examiner's attention is directed to claim 39 directed to "an isolated polypeptide which is a variant of the growth hormone protein, GH, and which includes the substitution Ile179Met," to claim 49 directed to "an isolated growth hormone polypeptide or protein which contains a Ile179Met substitution," and to claim 54 directed to "an isolated growth hormone polypeptide or protein which is characterised by possessing a reduced ability to activate the MAP kinase pathway." With reference to claim 54, it is noted (see at least the present Specification, Example 6 at *pp 32-33* and *pp 38-43*, see especially *page 41, ll 6-23*) that the growth hormone polypeptide or protein containing an Ile179Met substitution is clearly shown to possess reduced

ability to activate MAP kinase. This same polypeptide or protein forms the subject matter of new claims 141-148.

Thus, the subject matter of each of these claims is believed to provide a single general inventive concept, simply recited in alternative claiming language, which is the Applicant's right under U.S. patent practice. That is, a single general inventive concept (a polypeptide or protein which is a variant of the growth hormone protein, GH, and which includes the substitution Ile179Met) is set forth herein, which is believed to recite a general inventive concept which is both novel and which involves inventive step, and therefore is believed to constitute a special technical feature under the meaning of the PCT rules. The MPEP clearly recites that if these conditions are met, an objection of lack of unity of invention does not arise. MPEP §1850, at *page 1800-95*. The Examiner-cited J. Clin. Invest. article by Takahashi, being directed to a heterozygous single-base substitution (A → G) in exon 4 of the GH-1 gene of a single individual which results in a Gly to Asp substitution at codon 112 (see at least the *Abstract* of Takahashi), cannot be said to obviate this special technical feature of the present invention under any consideration of novelty or inventive step. Further, even if any question remains in the Examiner's mind, as noted above it is proper to give the Applicant the benefit of the doubt. See MPEP §1850 and PCT International Search and Preliminary Examination Guidelines Chapter 10, ¶10.04. Therefore, under PCT unity of invention rules it is believed that examination of at least these claims is also appropriate.

With regard to new claims 149-150, the Examiner accurately states (see page 4 of the Action) that the PCT rules provide for examination of a first claimed product, a first claimed method of making that product, and a first claimed method of using that product. Clearly, the subject of claim 149 is directed to a first claimed method of making the product as discussed above, with claim 150 being directed to a product made by that method. The discussion above as to why the PCT requirements of unity of invention are met, that is, that these claims are directed to a single general inventive concept and that Takahashi cannot be fairly said to render that concept non-novel or lacking in inventive step. Therefore, examination of these claims is believed to be proper, and is respectfully requested.

For the foregoing reasons, reconsideration of the lack of unity of invention finding, withdrawal of the restriction requirement, and examination of the claims remaining in the present application is believed to be merited and is respectfully requested. If any matters require further attention, the Examiner is requested to telephone Applicant's attorney to expedite issuance of the patent. Any fees, including the extra claims fees due, may be deducted from Deposit Account 11-0978.

Respectfully submitted,
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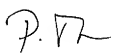

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